SECTION 4: 510(k) SUMMARY

This summary of safety and efficacy information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92.

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C. Date Prepared: January 2, 2011

D. Device Name: TropoCells Autologous Platelet Preparation Kit

Regulation number	21 CFR 864.9245
Regulation Name:	Automated blood cell separator
Class:	II
Product Code:	ORG
Product Name	Platelet and plasma separator for bone graft handling

E. Device Description:

The TropoCells Autologous Platelet Preparation Kit is a self-contained disposable kit containing two sterile blood separating vacuum tubes, two sleeve filters, various needles and a transferring device. Kit must be used in conjunction with a desktop centrifuge (not included).

F. Intended Use:

The TropoCells Autologous Platelet Preparation Kit is intended for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of blood at the patient point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

G. Substantial Equivalence:

The proposed kit uses the same technological characteristics, virtually the same materials, and performs identically to the predicate device previously permitted to market under 510(k) premarket notification. The predicate is the MyCells Autologous Platelet Preparation Kit (BK080057). Besides using a different product name, the only material difference between the two devices is that the TropoCells Kit does not include a vial containing 10 CC of a 10% calcium chloride solution.

H. Device Testing:

All of the performance and biocompatibility testing submitted in support of the MyCells Autologous Platelet Preparation Kit premarket notification is directly applicable to the TropoCells Autologous Platelet Preparation Kit.